LIGHT PHARMA
consulting | technology

PI QRM

Digitizing Quality Risk Management for Pharmaceutical Companies

The Challenge in Pharmaceutical Manufacturing

Global Operations

Pharmaceutical R&D and manufacturing operations span multiple facilities worldwide. A vast amount of knowledge is generated during research, development, and commercial manufacturing that must be effectively managed throughout the product lifecycle.

However, critical product and process knowledge often gets lost within organizations over time.

Complex Requirements

Essential activities such as new product launches, mergers and acquisitions, regulatory changes, and cost optimization frequently necessitate the transfer of knowledge and technology between different locations.

Quality Risk Management (QRM) is essential to ensure product quality, regulatory compliance, and patient safety—but managing complex risk assessments manually is resource-intensive and prone to errors.

Why Choose PI QRM?

1

Centralized Platform

Provides a collaborative platform with advanced analytics and customizable workflows to proactively manage risks while meeting international regulatory standards.

2

Knowledge Management

Serves as a knowledge management tool that enhances effectiveness and efficiency of knowledge transfers by making tacit knowledge and insights from past projects accessible for reuse.

3

Enterprise Solution

State-of-the-art enterprise software developed by Light Pharma to enhance and streamline the QRM process across your entire organization.

PI QRM simplifies and enhances the QRM process by integrating advanced tools, ensuring robust risk assessments, and enabling seamless collaboration across teams.

Centralized Risk Assessment Repository

Single Secure Platform

PI QRM consolidates all risk management data into one centralized location with secure access controls and real-time visibility.

Historical Data Access

Centralized access to historical risk data, assessments, and mitigation plans enables informed decision-making based on past experiences.

Real-Time Visibility

Monitor ongoing and completed risk assessments in real-time, ensuring teams stay aligned and informed throughout the process.

Structured Workflow and Collaboration

The PI QRM workflow ensures a seamless process from risk identification to mitigation with comprehensive tools for both manufacturing and analytical method assessments.

01

Process Mapping

Create Process Flow Diagrams to visualize workflows

02

Risk Analysis

Utilize Cause & Effect Matrix, Heat Maps, and Fishbone Diagrams

03

FMEA

Conduct Failure Mode and Effect Analysis and control strategies to summarize parameter information.

04

Configurable Risk Assessment

Configurable risk assessment workflows and templates tailored to the organization needs.

Integrated Intelligence: All information is integrated so that updating a Cause and Effect study or Heat Map automatically updates the corresponding FMEA or Fishbone Diagram. Automated notifications and task assignments keep teams aligned.

Leveraging Knowledge Across the Product Lifecycle

Capturing Knowledge

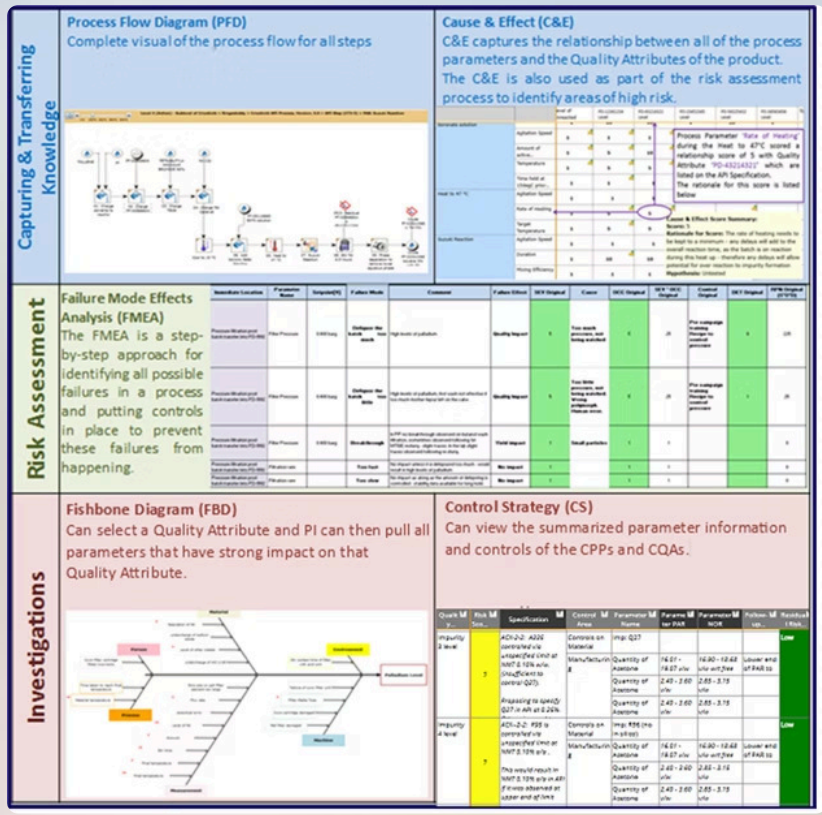
- Document critical insights during development
- Transfer knowledge between teams and facilities
- Preserve institutional expertise

Risk Assessments

- Conduct comprehensive risk evaluations
- Apply learnings from previous assessments
- Ensure consistent methodology

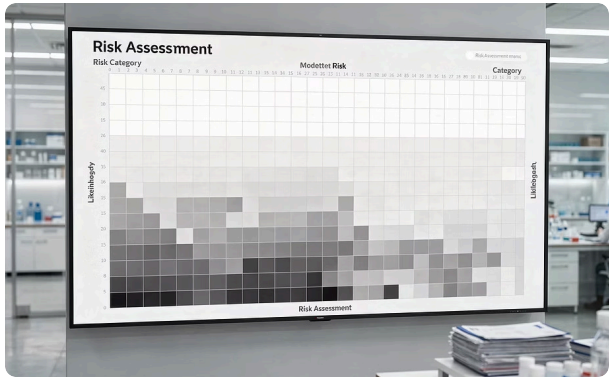
Quality Investigations

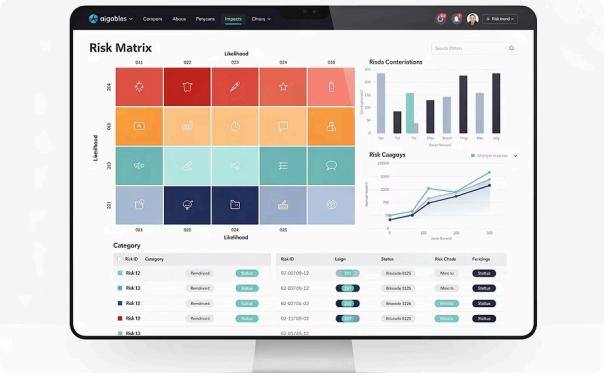
- Access historical data during investigations
- Identify root causes efficiently
- Implement corrective actions



Access PI QRM capabilities and knowledge at different stages of the product lifecycle, ensuring continuity and excellence from research through commercial manufacturing.

Comprehensive Risk Identification and Assessment



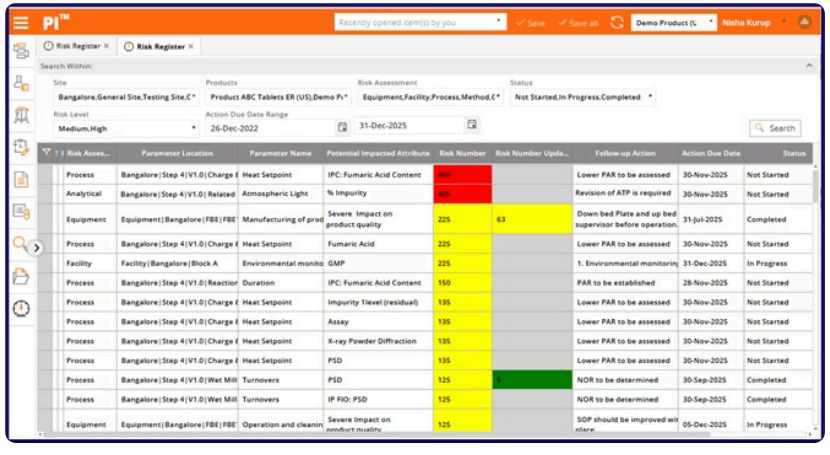


Advanced Risk Analysis

Define attributes, parameters, and critical control points for detailed risk analysis using industry-standard methodologies like FMEA.

Visual Risk Mapping

Visualize risk levels with intuitive heatmaps and risk matrices that make complex data immediately understandable for stakeholders.



Risk Register and Action Tracking

Access the Risk Register across Process, Method, Facility, Equipment, and Generic FMEAs. Track overdue actions through a consolidated report and monitor the implementation of mitigation plans with real-time status updates.

Customizable Reports and Dashboards

1

Flexible Reporting

Generate detailed risk assessment reports in Word or PDF formats for audits and reviews with user-friendly, customizable templates.

2

Interactive Visualization

Visualize key risk indicators with interactive reports like Heat Maps and KASA (Knowledge-aided Assessment & Structured Assessments).

3

Data Export

Export risk data for further analysis or regulatory submissions, ensuring seamless integration with your quality processes.

Regulatory Compliance and Security

Built for Compliance

PI QRM is fully complian-ready to meet global regulatory frameworks, data integrity and security at every level.

- **21 CFR Part 11 Compliance**

  Embedded e-signatures and comprehensive audit trails

- **ICH Q10 Alignment**

  Functionality aligned with principles of maintaining knowledge across the product lifecycle

- **Data Protection**

  Role-based access controls and secure storage for all risk-related records

- **Flexible Configuration**

  Configure workflows and templates tailored to your organization's requirements with admin-level customizations

The PI QRM Advantage

PI QRM is more than just a risk management tool—it's a comprehensive platform that digitizes and optimizes every stage of the QRM process.

Knowledge Independence

Develop a knowledge database that operates independently of individual reliance, preserving critical expertise.

Operational Excellence

Minimize manual effort and reduce human errors while enhancing process reliability and product quality.

Continuous Improvement

Proactively manage risks, ensure regulatory compliance, and gain actionable insights to drive innovation.

Empower your organization with PI QRM and redefine the standards of risk management in the pharmaceutical industry.

Investing in PI QRM is an investment in operational excellence, quality assurance, and regulatory compliance—enabling you to focus on delivering safe, effective products to market.